

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For: CONSERVED HBV AND HCV SEQUENCES USEFUL FOR GENE
SILENCING

MAIL STOP PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

**RENEWED PETITION UNDER 37 CFR §1.182 AND REQUEST TO CORRECT
PRIORITY UNDER 37 CFR §1.78**

Following the Decision in the Petition under 37 C.F.R. §1.182 filed December 4, 2009 in the above-noted application, Applicants submit this RENEWED PETITION under 37 CFR §1.182 to correct an inadvertent error on the part of the Applicant at the time of National Stage Entry (June 19, 2006) for the above-noted U.S. patent application. The petition seeks to establish a separate "bypass" Continuation-In-Part application of the original PCT (PCT/US2004/019229), claiming the benefit of priority of U.S. Provisional Application No. 60/638,294 filed December 22, 2004 in addition to U.S. Provisional Application No. 60/478,076, filed June 12, 2003. The petition includes a request under 37 CFR §1.78 to correct the priority claim for the Continuation-In-Part application. This RENEWED PETITION is accompanied by a Terminal Disclaimer disclaiming the terminal part of a patent to be granted on the Continuation-In-Part application equivalent to the period beginning on the filing date under 35 U.S.C. 111(a) of the Continuation-In-Part application and ending on the date a grantable petition under 37 C.F.R. 1.182 to create the Continuation-In-Part application is filed, along with the necessary fee for the disclaimer.

A Statement of Facts begins on page 2.

The **Request** begins on **page 4**.

Remarks begin on page 5.

Statement of Facts

1. On June 10, 2004 International Application PCT/US2004/019229 (also referred to herein as the "PCT application") was filed, claiming the benefit of priority from U.S. Provisional Application No. 60/478,076, filed June 12, 2003.
2. On December 22, 2004, US Provisional Application No. 60/638,294 (the '294 provisional) was filed, during the pendency of the PCT application and naming at least one inventor in common with the PCT application.
3. On December 12, 2005, a National Stage application was filed under 35 USC §371, which claimed priority to International Application PCT/US2004/019229, provisional 60/478,076 *and* the '294 provisional. This was prior to the expiry of the '294 provisional application. The contents of each of the PCT/US2004/019229, provisional 60/478,076 and the '294 provisional were incorporated by reference, as recited in the Application Data Sheet that accompanied the filing. A copy of the filing papers is annexed hereto for convenient reference (**Exhibit A**).
4. The §371 National Stage entry filing of December 12, 2005 (now USSN 10/560,377) included a complete copy of the specification, figures, claims, an application data sheet and a computer-readable sequence listing. The specification and figures filed with the National Stage entry filing of December 12, 2005 included additional nucleic acid sequences, a new Figure 15 and a new Sequence Listing.
5. On June 14, 2006, a Preliminary Amendment was filed, a copy of which is annexed hereto for convenient reference (**Exhibit B**). The Preliminary Amendment sought to amend the specification, claims and drawings to incorporate disclosure found throughout the '294 provisional priority document. An amended Sequence Listing in paper and computer-readable forms was also included with the Preliminary Amendment.
6. On July 1, 2009, a Non-Final Office Action was mailed from the USPTO to the Attorney of Record (the Office Action was re-mailed by the USPTO on September 9, 2009 after Applicants' representative informed the Examiner that PAIR listed the Office Action as

having been returned to the USPTO by the Postal Service). The Office Action rejected the material from the '294 priority application introduced to the specification by means of the June 14, 2006 preliminary amendment as being "new matter."

Request

Based on the facts as stated above, Applicants respectfully request in this RENEWED PETITION that a separate U.S. Utility application be established under 35 U.S.C. §120 as a Continuation-In-Part of PCT/US2004/019229, with priority to U.S. provisional application 60/478,076, and to U.S. provisional application 60/638,294. The Commissioner is authorized to charge any and all fees necessary for establishing such application to Deposit Account 50-0850, referencing matter No. 051058-034000. This includes filing fees required for the newly generated application established under §120, the fee under 37 C.F.R. §1.17(f) required for this petition under 37 C.F.R. §1.182 and the fee for the accompanying terminal disclaimer.

Applicants submit that the claim for priority to the '294 provisional application was made in a timely manner with the December 12, 2005 National Stage filing, but acknowledge that the claim was improper in the context of the §371 filing. Thus, to the extent that it is necessary to achieve the purpose of generating a Continuation-In-Part application properly claiming the priority of the PCT, the 60/478,076 provisional application *and* the '294 provisional application, applicants hereby request the correction of the priority claim under 37 C.F.R. §1.78 for the resulting Continuation-In-Part application to reflect priority from PCT/US2004/019229, filed June 10, 2004, U.S. provisional 60/478,076 filed June 12, 2003, and U.S. provisional 60/638,294 filed December 22, 2004. To the extent necessary, Applicants authorize the Commissioner to charge the fee specified under 37 C.F.R. §1.78(t) for the correction of the priority claim under 37 C.F.R. §1.78.

Marked-up and clean copies of the Continuation-In-Part specification including the disclosure from the '294 application are included herewith, as is an Application Data Sheet showing the application as a Continuation-In-Part of the parent PCT.

REMARKS

The currently pending application, Serial No. 10/560,377, is being amended with the response to the outstanding Office Action to cancel the material added by preliminary amendments made both at the time of filing and on June 14, 2006. Applicants intend for that application to remain pending minus the material designated as new matter in the Office Action issued September 4, 2009.

It is understood that in order to properly claim the benefit of the '294 provisional application or to incorporate material in that application in the National Stage application, the National Stage entry should have been made under §120, rather than §371, which does not permit priority claims or disclosure beyond that which is established in the international application. For entry under §371, a copy of the specification, claims and drawings is not required. However, the National Stage filing *included* a complete copy of the specification, claims, and drawings and therefore contained all of the elements necessary for entry under 35 USC §120 as a Continuation or Continuation-In-Part application as of the December 12, 2005 date of filing. The Application Data Sheet submitted concurrently with the National Stage application incorporated the contents of each of the PCT application, U.S. provisional application 60/478,076 and the '294 provisional application in their entireties.

Applicants' representatives Mark FitzGerald and David Crosby have been in telephone contact with Debra Brittingham in the Office of PCT Legal Administration. Ms. Brittingham indicated that given the circumstances, and under Patent Office policy, Applicants should be entitled to spin out a separate Continuation-In-Part application that permits the incorporation of the material in the '294 provisional application at least as of the December 12, 2005 National Stage entry date, without loss or surrender of rights. Where the filing timely satisfied the requirements for entry under §120 but counsel erroneously recited entry under §371, it is a matter of fairness to the Applicant that they be given the opportunity to correct the designation of the application to prevent the loss of rights. Ms. Brittingham indicated that the present petition under 37 C.F.R. §1.182 and necessary fee under 37 C.F.R. §1.17(f), plus filing fees for the new application and a request under 37 C.F.R. §1.78 to correct the priority claim would be necessary to establish the separate Continuation-In-Part application.

The Petition filed December 4, 2009 was dismissed, the Patent Office indicating that Applicants had filed a proper petition under 37 C.F.R. 1.182, identifying the specific papers filed which are to be used in the newly-created application under 35 U.S.C. 111(a), but stating that

“because a significant period of time has elapsed from the filing of the above-captioned application, before such petition can be granted, applicant is required to file a terminal disclaimer under the provisions of 37 C.F.R. 1.321(b) disclaiming the terminal part of the term of a patent to be granted equivalent to the period between the filing date of a grantable petition under 37 C.F.R. 1.182 to create the CIP application and the filing date under 35 U.S.C. 111(a) of such application.” The dismissal also stated that the decision on the petition under 37 C.F.R. 1.78 will be held in abeyance pending resolution of any renewed petition under 37 C.F.R. 1.182.” Applicants herewith submit this RENEWED PETITION, including a Terminal Disclaimer and the necessary fee.

To the extent that they are necessary for a RENEWED PETITION, the following fees are authorized to be charged to Deposit Account 50-0850, referencing 051058-034000: (i) fee for petition under §1.182, (ii) fee for correction of priority under 37 CFR §1.78, (iii) fees for a new U.S. Utility application, (iv) and the terminal disclaimer fee under 37 C.F.R. 1.20(d). Should any other fees be associated with this submission, the Applicant hereby authorizes the Commissioner to charge them to said Deposit Account. Any overpayments should also be credited to said Deposit Account.

Applicants respectfully request that if this petition is deficient in any way that the undersigned be contacted at the number below to expedite resolution of the defect(s).

Respectfully submitted,

Date: September 9, 2010

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